DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 4 2001

Dr. Heather Anderson
Regulatory Affairs
Randox Laboratories Ltd.
Biochemical Manufacturers
Ardmore, Diamond Road
Crumlin, Co. Antrim
United Kingdom, BT29 4QY

Re: k011393
Trade/Device Name: Phenytoin
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin test system
Regulatory Class: Class II
Product Code: DIP
Dated: November 15, 2001
Received: November 19, 2001

Dear Dr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Known K011393

Device Name: PHENYTOIN

Indications For Use :

The Randox Laboratories Ltd. Phenytoin Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of phenytoin in serum. The method is a latex-enhanced immunoturbidimetric assay based on the principle of measuring changes in scattered light. Latex particles are coated with phenytoin and, in the presence of phenytoin antibody solution, rapid agglutination occurs. When a sample containing phenytoin is introduced the agglutination reaction is partially inhibited, slowing down the agglutination process. The rate of agglutination is inversely dependent on the concentration of phenytoin in the sample. By monitoring the change in scattered light as a change in absorbance, a concentration curve can be obtained. The actual change in absorbance is inversely proportional to the concentration of phenytoin in the sample.

Measurements obtained by this device are used in the diagnosis and treatment of phenytoin use or overdose and in monitoring levels of phenytoin to ensure appropriate therapy.

These Application Sheets have been developed for the Hitachi 717 and Advia 1650 analysers and must be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

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Divis ...ory Devices

510(k) Number K011393

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)